

# EXHIBIT H

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2 IN THE UNITED STATES DISTRICT COURT  
3 DISTRICT OF MINNESOTA

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4 IN THE MATTER OF )  
5 IN RE BAIR HUGGER FORCED AIR )  
6 WARMING )  
7 PRODUCTS LIABILITY LITIGATION )  
8 Plaintiff, )  
9 3M COMPANY AND ARIZANT ) PRETRIAL ORDER NO: 7  
10 HEALTHCARE INC. ) Protective Order  
11 Defendant. ) MDL No. 15-2666

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11 DEPOSITION OF PAUL MCGOVERN

12 VOLUME II

13 Thursday, January 5, 2017  
14 AT: FAEGRE BAKER DANIELS LLP  
15 Taken at:  
16 7 Pilgrim Street  
17 London EC4V 6LB  
18 United Kingdom

19  
20 Court Reporter:

21 Louise Pepper: Accredited Real-time Reporter  
22 Videographer: Simon Addinsell

23

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25 JOB NO. 117121

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2 APP E A R A N C E S  
3  
4 Appear for the Plaintiff:  
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6 CIRESI CONLIN  
7 225 South 6th Street  
8 Minneapolis, MN 55402

9 GENEVIEVE ZIMMERMAN  
10 MESHBESHER & SPENCE  
11 1616 Park Avenue  
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13 Appear for the Defendant:

14 MR. COREY GORDON  
15 BLACKWELL BURKE  
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18 MS. KATHERINE NEWMAN  
19 FAEGRE BAKER DANIELS  
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21 Appear for the Witness:

22 MR. ANDREW HEAD  
23 MR. BRYAN SHACKLADY  
24 FORSTERS  
25 31 Hill Street  
London W1J 5LS

1  
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19 208, Bates stamped  
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20 Exhibit 5 Document entitled .....306  
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24 Exhibit 7 Email chain dated 8-11 .....309  
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2 Exhibit 9 Document entitled "Do .....324  
3 Forced Air Warming Devices  
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6 Exhibit 10 Email chain between .....336  
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13 dated 21 February 2010,  
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21 Exhibit 15 Email chain between .....359  
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2 Exhibit 17 Email chain between .....372  
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12 reduction in periprosthetic  
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13 or warming technique?", dated  
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14 Exhibit 20 Journal of Bone and .....391  
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20 Exhibit 22 Journal of .....403  
21 Tissueviability paper entitled  
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23 study comparing the jubilee  
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24 adhesive dressing for total  
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1 Exhibit 23 Email chain between .....410  
 2 Mark Albrecht and Mike Reed,  
 3 "Full workup of stats you  
 4 requested", dated 29 November,  
 5 2011.  
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 7 Exhibit 24 Email from Mark .....416  
 8 Albrecht to Scott Augustine,  
 9 with attachment, dated  
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 16 on OR Ventilation Performance  
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 19 Belani\_000002-000039  
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 21 Exhibit 26 Email from Mark .....454  
 22 Albrecht to Paul McGovern and  
 23 others, "Fwd: A&A Decision for  
 24 MS#: AA-D-11-01334", dated 25  
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 27 Exhibit 27 Email chain between .....455  
 28 Mark Albrecht, Mike Reed and  
 29 others, "Fwd: A&A DEcision for  
 30 MS#: AA-D-11-01334R1", dated  
 31 11 January 2012.  
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 33 Exhibit 28 Spreadsheet, Bates .....461  
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1 DR. PAUL MCGOVERN  
 2 PROCEEDINGS  
 3 THE VIDEOGRAPHER: This is Day 2 of the deposition  
 4 of Dr. Paul McGovern. The deposition started yesterday  
 5 4 January, today is 5 January 2017, and it is 9:24 a.m.  
 6 This is the beginning of DVD 1 in volume 2 of Dr. McGovern's  
 7 deposition. Everybody who was in the room yesterday is here  
 8 today.  
 9 Can I remind the witness he was sworn in  
 10 yesterday and is still under oath. Can you --  
 11 THE WITNESS: Yes.  
 12 THE VIDEOGRAPHER: You're on the record, counsel.  
 13 It is 25 past 9.  
 14 EXAMINATION BY MR. SACCHET:  
 15 BY MR. SACCHET:  
 16 Q. Good morning, Dr. McGovern.  
 17 A. Good morning.  
 18 Q. As I mentioned yesterday, my name is Mr. Sacchet,  
 19 and I represent the plaintiffs 3M. Yesterday my learned  
 20 friend on the other side reviewed some of the ground rules  
 21 for the deposition. I'm going to go through few more today,  
 22 just to make sure we're on the same page with respect to the  
 23 procedures for our conversation. As you know, I'll be  
 24 asking you questions under oath and you'll be responding to  
 25 them. If at any time you don't understand a question or if

1 DR. PAUL MCGOVERN  
 2 you don't hear the question, please let me know, okay?  
 3 A. Yes.  
 4 Q. As was mentioned yesterday, it's best for the  
 5 record and the court reporter, if I ask a question, that you  
 6 let me finish asking the question before you answer, and  
 7 I'll do the same with respect to you in refraining from  
 8 asking a question before you've finished your answer.  
 9 Please provide audible "Yes" or "No" answers with respect to  
 10 the questions as opposed to a nodding or shaking of the  
 11 head. Is that agreeable?  
 12 A. Yes.  
 13 Q. And if at any time you need a break, just let me  
 14 know, and I'll find an appropriate spot to pause.  
 15 A. Sure.  
 16 Q. Before we jump into your background, with respect  
 17 to your educational and professional history, just a few  
 18 preliminary items. You've never met me before, have you?  
 19 A. Not before yesterday, no.  
 20 Q. And prior to yesterday, you'd never spoken to me  
 21 before, be it via e-mail or phone?  
 22 A. That is correct.  
 23 Q. You've never spoken to any members of the  
 24 plaintiff's counsel in this matter, have you?  
 25 A. That is correct.

1 DR. PAUL MCGOVERN  
 2 Q. Have you ever spoken to anyone on the side of the  
 3 defense, prior to yesterday?  
 4 A. I'd received communications from various people on  
 5 the side of the defense. I have only communicated with them  
 6 through my lawyers.  
 7 Q. Okay. Do you recall who those individuals were  
 8 that attended the --  
 9 A. Stephen Llewellyn, from Faeger Baker Daniels.  
 10 I received a LinkedIn message from a lawyer in the United  
 11 States, but I don't remember their name.  
 12 Q. Do you recall the content of the message?  
 13 A. It was similar to the initial contact from Stephen  
 14 Llewellyn, saying that 3M would like to depose me, and  
 15 asking me to get back in touch to arrange that.  
 16 Q. And did you get back in touch to arrange that?  
 17 A. I did not reply to the LinkedIn message at all, and  
 18 I replied to Stephen Llewellyn through my lawyers when  
 19 I arranged legal representation.  
 20 Q. Okay. So other than contact via your attorney,  
 21 you've had no personal contact with anyone on the other  
 22 side?  
 23 A. That is correct.  
 24 Q. I know you spoke a little bit yesterday about your  
 25 background as well, and I'm going to review some of that

<p style="text-align: center;">Page 406</p> <p>1 DR. PAUL MCGOVERN  2 in jubilee dressing that occurred during the time in which  3 the data was collected for the McGovern study impacted  4 infection rates?</p> <p>5 MR. C. GORDON: Object to the form of the  6 question: lack of foundation, incomplete hypothetical.</p> <p>7 A. It's not possible to say, in my opinion. The  8 numbers in this study are too small. You have a number of  9 patients that is 124, and the numbers are too small to be  10 able to draw a meaningful conclusion in terms of infection,  11 with regard to these two variables, in my opinion.</p> <p>12 BY MR. SACCHET:</p> <p>13 Q. So if I could point out, to the extent that this  14 would change your mind, the asterisks which are denoted in  15 the right-hand column of the standard adhesive dressing  16 column; do you see those?</p> <p>17 A. Yes.</p> <p>18 Q. And a single asterisk stands for a P value of less  19 than 0.05; correct?</p> <p>20 A. Mm-hm, yes.</p> <p>21 Q. And a double asterisk stands for a P value of 0.01  22 and less?</p> <p>23 A. Yes.</p> <p>24 Q. And three asterisks stands for a P value of 0.001  25 or less; correct?</p>	<p style="text-align: center;">Page 407</p> <p>1 DR. PAUL MCGOVERN  2 A. Yes.  3 Q. The infection row has no such asterisk in it,  4 does it?</p> <p>5 A. That's correct.  6 Q. So, because we established earlier that statistical  7 significance begins at 0.05, which is a single asterisk ...  8 A. Right.  9 Q. ... presumably this 0 percent infection rate, the  10 difference between 0 and 0 is non-significant; correct?</p> <p>11 A. No, that's not how I would interpret this. There  12 is no data to draw a meaningful conclusion from. You need  13 to have some data, by my understanding, to be able to draw  14 a conclusion of statistical significance. You can't comment  15 on whether these data are statistically significant. If one  16 were designing this study purely to look at infection rates  17 between the two dressings, it is likely that the study would  18 need to include more patients and the study -- and to ensure  19 it was sufficiently powered to be able -- "powered" meaning  20 to have enough patients in it -- to see enough infections to  21 be able to draw a meaningful conclusion.</p> <p>22 The fact that there were no infections in 124  23 patients is not surprising, because infection rates are  24 generally low. This is a problem of research in this  25 area. Because infection is rare, thankfully, you need</p>
<p style="text-align: center;">Page 408</p> <p>1 DR. PAUL MCGOVERN  2 large numbers of patients in studies to see if one  3 intervention has a difference with another  4 intervention, in terms of infection rates. In my  5 opinion, this study does not demonstrate superiority of  6 one adhesive dressing over another, purely in terms of  7 infection.</p> <p>8 Q. Fair enough --  9 A. It may for other conditions, such as blistering and  10 leakage, but for infection -- because those are more  11 common -- consequences post-operation, and the study appears  12 to have been adequately powered to identify those  13 differences and state statistical significance. But for  14 infection, there were not enough incidences of infection to  15 be able to draw meaningful conclusions, or a difference  16 between the two.</p> <p>17 Q. Are you aware of any paper that is adequately  18 powered that shows that a change from a standard adhesive  19 dressing to a jubilee dressing would statistically  20 significant -- significantly alter infection rates among  21 arthroplasties?</p> <p>22 A. I am not aware of any such paper.  23 Q. Are you aware of any published papers that  24 suggest -- I should say that find statistically significant  25 differences between joint infection rates from the use of</p>	<p style="text-align: center;">Page 409</p> <p>1 DR. PAUL MCGOVERN  2 MSSA screening versus non-screening?</p> <p>3 A. Sorry, could you say that again, please?</p> <p>4 Q. Are you aware of any evidence that is statistically  5 significant that suggests that the use of MSSA screening  6 significantly impacts the rate of deep joint infections  7 among patients?</p> <p>8 A. I'm not aware of any such papers.</p> <p>9 Q. Are you aware of any evidence that pre-warming,  10 when used in combination with intraoperative warming,  11 significantly impacts deep joint infection rates among  12 patients?</p> <p>13 A. I am not aware of papers which provide evidence of  14 that.</p> <p>15 Q. Have you seen an article by Mr. Reed and another  16 individual, bearing the last name Refaie, which analyzed the  17 NHS SSI bundle?</p> <p>18 A. I presume you mean Northumbria Foundation Trust.  19 I am aware that Mr. Reed and Mr. Refaie have done research  20 together. I may have seen such paper but I don't remember.</p> <p>21 Q. Do you recall Mr. Reed, in that paper, making the  22 statement: "A switch to the alternative conductive fabric  23 warming led to a significant decrease in deep joint  24 infections"?</p> <p>25 A. I -- that statement sounds familiar but I don't</p>

<p style="text-align: center;">Page 410</p> <p>1 DR. PAUL MCGOVERN 2 remember reading it in a paper. 3 Q. Would you have any reason to doubt, if Mr. Reed 4 made such a statement, the accuracy of such a statement? 5 MR. C. GORDON: Object to the form of the 6 question: lack of foundation, assumes facts not in evidence. 7 A. If Mr. Reed indeed made that statement in a paper, 8 I'd have no reason to doubt the veracity of that statement. 9 BY MR. SACCHET: 10 Q. Are you aware of the fact that after the McGovern 11 paper was published in the Journal of Bone and Joint 12 Surgery, that additional data supported an elevated 13 odds-risk ratio? 14 MR. C. GORDON: Object to the form of the 15 question: assumes facts not in evidence, incomplete 16 hypothetical. 17 A. I was not. 18 BY MR. SACCHET: 19 Q. Okay. 20 (Exhibit 23 marked for identification) 21 Q. That's an e-mail entitled "Full workup of the stats 22 you requested"; correct? 23 A. Yes. 24 Q. And there is an e-mail from Mr. Albrecht to 25 Mr. Reed, and you are cc'd on the e-mail on November 29,</p>	<p style="text-align: center;">Page 411</p> <p>1 DR. PAUL MCGOVERN 2 2011; correct? 3 A. Yes. 4 Q. And there is an attachment called "Results"; 5 correct? 6 A. Yes. 7 Q. And if you turn the page, there is a table. Does 8 this table resemble the table in the published McGovern 9 study? 10 A. It does resemble it. I'll check if it is the same. 11 Q. There are different data points, but just in terms 12 of the style and form of the table? 13 A. Err ... 14 Q. It is exhibit 13, to make sure you're on the right 15 one. 16 A. I'm there. I'm on exhibit 13. Which table are you 17 referring to? Table 1 in exhibit 13? 18 Q. I am looking at -- yes. No. 19 A. Table 2. 20 Q. Yeah, the lower half of Table 2. I mean with parts 21 of the lower half, as well. 22 A. Yes, I would agree this is similar in form to part 23 of Table 2 in what you refer as to the "McGovern paper". 24 Q. Okay. And if we look at that table in the e-mail 25 thread, for a conductive fabric, number developing</p>
<p style="text-align: center;">Page 412</p> <p>1 DR. PAUL MCGOVERN 2 infection, 7; correct? 3 A. Oh, yes. 4 Q. Number not developing infection, 792; correct? 5 A. Yes. 6 Q. For a total population of 709 patients who received 7 conductive fabric warming; correct? 8 A. Yes. 9 Q. That number is significantly larger than the total 10 population of individuals who received conductive fabric 11 warming in the final published paper, exhibit 13; correct? 12 A. That number is larger. To say it was significantly 13 larger would require a statistically significant test. So 14 be careful about using the words "statistically 15 significantly", but it is a larger number. 16 Q. How about double? 17 A. Let's see. Conductive fabric 792 versus 368. Yes, 18 I think that's a reasonable thing to say. 19 Q. Okay. And if we go back to the text of the e-mail, 20 Mr. Reed writes back to Mr. Albrecht and copies you in and 21 says, in the last line of the first paragraph: 22 "You are 3.6 times more likely to get an 23 infection on FAW than CFW." 24 Do you see that? 25 A. Yes. It phrases a question, but yes.</p>	<p style="text-align: center;">Page 413</p> <p>1 DR. PAUL MCGOVERN 2 Q. Yes. Do you have any reason to doubt Mr. Reed's 3 statement to that effect? 4 A. It appears that Mr. Reed is asking if that is what 5 the data is showing in this table. 6 Q. And do you see, in the table itself, a demarcation 7 of 3.6 on the right-hand side of the odds ratio? 8 A. I do. 9 Q. So in fact Mr. Reed was referring to this table; 10 correct? 11 A. That is -- seems likely. 12 Q. And this table was sent as a results attachment 13 from Mr. Albrecht? 14 A. Yes. 15 Q. You have no reason to doubt Mr. Albrecht's ability 16 to conduct statistical analysis of data, do you? 17 A. None whatsoever. 18 Q. You have no reason to doubt that, based on this 19 patient population of those who received conductive fabric 20 warming, which is double the size of the patient population 21 in the McGovern study, that there was a 3.6 odds ratio? 22 A. That is what this data appears -- (overspeaking) -- 23 MR. C. GORDON: Object to the form of the 24 question. 25 THE COURT REPORTER: Sorry, can you repeat the</p>

<p>1 DR. PAUL MCGOVERN  2 objection, please.  3 MR. C. GORDON: Form.  4 A. That is what this data appears to show.  5 BY MR. SACCHET:  6 Q. So this data shows there is a 3.6 times increase in  7 infection as a result of using forced-air warming devices  8 compared to conductive fabric warming devices; correct?  9 A. That is what --  10 MR. C. GORDON: Object to the form of the  11 question.  12 A. That is what this table appears to show.  13 BY MR. SACCHET:  14 Q. And both this odds ratio and the odds ratio  15 presented in the final published McGovern study are both  16 above 3.0; correct?  17 A. Yes.  18 Q. So, based on this data in the increased patient  19 population of those who received conductive fabric warming,  20 this data corroborates the fact that there is at least  21 a three times more likely chance that patients who received  22 forced-air warming developed an infection, compared to those  23 who received conductive fabric warming?  24 MR. C. GORDON: Object to the form of the  25 question.</p>	<p>1 DR. PAUL MCGOVERN  2 A. This data -- I can't agree with the term  3 "corroborates the fact". The fact is not --  4 BY MR. SACCHET:  5 Q. Also shows?  6 A. Yeah. Could you just repeat the phrase, please, or  7 rephrase that? Or --  8 Q. I'll rephrase the question.  9 Based on the data presented in this table and the  10 data presented in the McGovern study, both studies for  11 both datasets show that there was a three -- at least  12 a three times more likely chance that a patient  13 developed an infection after using forced-air warming  14 than conductive fabric warming?  15 MR. C. GORDON: Object to the form of the  16 question.  17 A. Yes. Patients who were in the group with  18 forced-air warming on this data appear to have had a three  19 times or more higher incidence of infection compared to the  20 conductive fabric group of patients for this study.  21 THE COURT REPORTER: Can I just ask you to stop  22 for 30 seconds, sorry.  23 THE VIDEOGRAPHER: Going off at two minutes past  24 three.  25 (3:02 p.m.)</p>
<p>1 DR. PAUL MCGOVERN  2 (Break taken.)  3 (3:04 p.m.)  4 THE VIDEOGRAPHER: Back on the record at four  5 minutes past three.  6 (Exhibit 24 marked for identification)  7 BY MR. SACCHET:  8 Q. Mr. McGovern, are you aware of any data that's been  9 collected regarding other healthcare facilities that have  10 shown a decreased rate of infection after the switch from  11 forced-air warming devices to conductive fabric warming  12 devices?  13 A. I am not.  14 Q. If you could take a look at the exhibit which was  15 just marked. The first page is an e-mail; is that correct?  16 A. Yes.  17 Q. From Mr. Albrecht to Scott Augustine, bearing the  18 subject line "Results" with attachments "MA_edits"; correct?  19 A. Yes.  20 Q. And Mark Albrecht states:  21 "I've updated the statistics in the white  22 paper under **MA_edits.doc**."  23 A. Yes.  24 Q. "The updates include:  25 "The statistics in the Table for all centers and</p>	<p>1 DR. PAUL MCGOVERN  2 the pooled result[s]  3 "The statistics in the discussion for the updated  4 McGovern numbers provided as provided [sic] in the  5 text."  6 Do you see that?  7 A. Yes.  8 Q. In the third paragraph it says:  9 "I think this is the best modeling approach  10 (i.e. a conservative one) for the data you have,  11 especially if you expect these results to be critically  12 questioned down the road."  13 Do you see that?  14 A. Yes.  15 Q. Okay. And the next page is a document entitled  16 "Forced-air warming link to periprosthetic total joint  17 replacement infections"; correct?  18 A. Yes.  19 Q. And the "Methods" says:  20 "To investigate whether the rising  21 contaminants from the waste FAW heat are linked to  22 PJIs, we retrospectively collected joint implant  23 infection data from three hospitals. We compared PJI  24 rates during a period of forced-air warming to PJI  25 rates during a period of free-air conductive fabric</p>